65. The immunologically isolated stromal cells of claim 37, wherein said cells are cultured for at least one hour.

66. The immunologically isolated stromal cells of claim 37, wherein said cells are cultured for about three to about thirty days.

67. The immunologically isolated stromal cells of claim 37, wherein said cells are cultured for about five to about fourteen days.

68. The immunologically isolated stromal cells of claim 37, wherein said cells are cultured for about seven to about ten days.

REMARKS

The present Preliminary Amendment accompanies a Response to the Restriction Requirement dated March 30, 1999 (Paper No. 7) wherein Applicants have elected to prosecute the claims of Group V, claims 37 and 38. The Restriction Requirement is being filed simultaneously herewith along with a Petition for a one month extension.

Claim 37 has been amended and new claims 55-68 have been added in the present application. Claim 37 has been amended to more clearly point out that the gene construct in the claimed cells is operably linked to regulatory elements. The amendment is a grammatical change amply supported throughout the specification as filed, specifically, at, *e.g.*, page 16, line 36, to page 17, line 1; page 17, lines 13-16, and lines 31-35; page 19, lines 7-10.

Further, new claims 55-68 have been added which depend from claim 37 and which claim subject matter included in originally filed claims 1-54 and which is supported by the disclosure of the specification as filed. Thus, no new matter has been added by way of the addition of these claims. More specifically, the new claims are supported by the specification as filed as follows.

Claim 55, depending from claim 37 recites that the cells comprise a herpesvirus thymidine kinase. Support for this recitation is found in the specification at page 20, lines 15-25.

Claim 56, depending from claim 37 recites that the beneficial protein is selected from the group consisting a type II procollagen, a type II collagen, a cystic fibrosis protein, a human growth hormone, an obesity factor, and a human Factor VIII. This recitation is supported

throughout the specification and, more specifically, by the disclosure provided in page 10, line 2, to page 13, line 2; page 15, lines 4-32; page 16, lines 17-34; Table 4; and Table 5.

Claim 57, depending from claim 37 recites that the cells are transfected using methods selected from the group consisting of calcium phosphate precipitation transfection, DEAE dextran transfection, electroporation, microinjection, liposome-mediated transfer, chemical-mediated transfer, ligand-mediated transfer, and recombinant viral vector transfer. Support for this recitation is found at page 7, lines 24-27; page 8, lines 6-13; page 21, lines 10-30.

Claim 58, depending from claim 37 recites that the cells are donor matched. Support for this claim is found in the specification on page 9, line 9.

Claim 59, also depending from claim 37 recites that the regulatory elements comprise at least one of a promoter, a polyadenylation signal, an initiation codon, and a stop codon. Support for this claim is found in the specification on page 17, lines 27-29.

Claim 60, depending from claim 37 recites that the promoter is selected from the group consisting of a cytomegalic virus promoter, a SV40 promoter, a retroviral promoter, a human procollagen I promoter, a human procollagen II promoter, a human procollagen III promoter, a COL1A1 promoter, and a COL2A1 promoter. Support for claim 60 is found in the specification on page 18, line 4, to page 19, line 2.

Claim 61, depending from claim 37 recites that the polyadenylation signal is selected from the group consisting of a human collagen I polyadenylation signal, a human collagen II polyadenylation signal, and a SV40 polyadenylation signal. Support for this recitation is found in the specification on page 19, lines 3-6.

Further, claim 62, depending from claim 37 recites that the gene construct also comprises a second gene. Support for this recitation is found in the specification on page 21, lines 30-31. Further, claim 63 recites that the second gene is a detectable marker. Support for claim 63, which also depends from claims 37 and 38, is found in the specification on page 21, lines 31-32. Additionally, claim 64, recites that the marker is an antibiotic resistance gene. This recitation is supported by the disclosure provided in the specification on page 21, lines 31-34.

Claims 65 through 68 recite that the cells are culture for at least one hour (claim 65), for about three to about thirty days (claim 66), for about five to about fourteen days (claim 67), and for about seven to about ten days (claim 68). Support for these claims is found in the specification on page 22, line 3, to page 23, line 17.

Since each of the added claims 55-68 is supported by the specification as filed, no new matter has been added by way of these additions.

Therefore, Applicants respectfully request examination of claim 37, 38, and 55-68 on the merits.

Respectfully submitted,

DARWIN J. PROCKOP *ET AL.*

May 25, 1999
(Date)

By: Kathryn Doyle

KATHRYN DOYLE, Ph.D., J.D.
Registration No. 36,317
PANITCH SCHWARZE JACOBS & NADEL, P.C.
One Commerce Square -- 22nd Floor
2005 Market Street
Philadelphia, PA 19103-7086
Telephone: (215) 567-2020
Direct Dial: (215) 965-1284
Facsimile: (215) 567-2991
E-Mail: kdl@psjn.com

KDL/moh